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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/951,733	10/16/1997	LEA ANNE HARRINGTON	A-433B	1921

21069 7590 03/22/2006

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EXAMINER	
BUGAISKY, GABRIELE E	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/951,733	HARRINGTON ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) 22-25,31 and 32 is/are withdrawn from consideration.

5)☒ Claim(s) 5 and 33 is/are allowed.

6)☒ Claim(s) 1-20, 26-30 is/are rejected.

7)☒ Claim(s) 21 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Allowable Subject Matter

The indicated allowability of claim 1-21, 26-30 and 33 is withdrawn in view of the newly discovered reference(s) to Cech et al. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2-3 and 7-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims as written, read upon the naturally occurring nucleic acid and do not suggest "the hand of man". Amendment could overcome this rejection, e.g., recitation of "isolated nucleic acid" in claims 2-3, "cloning vector" in claims 7-12, and "isolated host cell" in claims 13-18.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims encompass *in vivo* cells of any transgenic non-human multicellular organism, including mammals. The specification has not provided one of skill in the art with adequate description of transgenic animals comprising the polynucleotide encoding the described telomerase.

The specification discusses host cells on pages 27-30, and appears to focus on cultured cells. It is silent, however, whether only cultured cells/cell lines are considered "host cells".

The specification also states on page 12, lines 15-25 that the invention includes non-human mammals in which the telomerase gene is overexpressed; thus, reasonably the term "host cell" can be considered to include cells of the transgenic non-human mammal.

To determine whether there is correspondence between the generic invention of the claims and the written description, is necessary to determine whether the description conveys to one skilled in the relevant art that applicant was in possession of the claimed genus at the time the application was filed. To this end, it is appropriate to inquire whether a number of species representative of the genus are described in complete structural terms or, alternatively, with reference to other identifying characteristics, *e.g.*, partial structure, chemical properties, functional properties, *etc.* What constitutes a "representative number" of species for any given genus depends in part on whether the level of skill in the art, the teachings in the disclosure, or

teachings in the prior art establish predictability as to the structural properties characteristic of the genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

No transgenic mammals have been provided and thus the skilled artisan cannot envision the detailed phenotype of the encompassed organisms, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of obtaining it. The product itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Claims 13-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated transgenic cells and plant tissues, does not reasonably provide enablement for transgenic animal cells *in vivo*. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As stated above, there is inadequate written description for transgenic animal cells *in vivo*. What is not described cannot be considered enabled. Amendment to recite "isolated" could overcome this rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each claim recites " . . . wherein the codon for aspartic acid at amino acid position . . . of DEQ ID NO:19. . . " SEQ ID NO:19 is a nucleic acid sequence and cannot have amino acid positions; presumably it was intended to recite "SEQ ID NO:20".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 6, 7, 10, 12, 13, 16, 18-20, 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by CECH *et al* (US patent 6,261,836). The patent reveals the sequences of

telomerase DNAs from several different species including human. Claims 3-12 of the patent recite the nucleotides, construct and methods of preparing recombinant human telomerase. The sequence encoding human telomerase 2 is presented as SEQ ID NO:224; and is identical to instant SEQ ID NO:19, nucleotides 13-3798, with a single substitution at instant nt 3784 (that does not change the codon). The start codon of the encoded telomerase is at nt 67 of SEQ ID NO:19, and nt 55 of SEQ ID NO 224 of the patent, With respect to claim 6, the Examiner reads the claim as that the full length telomerase cDNA of the reference encodes amino acids 640-940 of the polypeptide of SEQ ID NO:14. Amendment to recite a "polypeptide consisting of . . . " could overcome this rejection. With respect to the recited subject matter of instant claims 26-27, expression of the telomerase in a cell would inherently increase the proliferation rate and/or the telomerase activity of/in the cells.

Claims 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech *et al* (US patent 6475789) . The disclosure reveals in Example 2 (column 107) the correlation between telomerase expression and cell immortality. The patent also reveals mutant plasmids, in which Asp869 is substituted with ala (see, e.g., pGRN130 column 170, lines 64-67, column 171, lines 1-8) The inventors also show in column 198 lines 14-17, that a mutant enzyme with Asp868 to ala was produced and tested to be inactive.

Conclusion

SEQ ID NO: 19 contains an internal substitution at nt 3784 when compared to SEQ ID NO:224 of Cech et al. (US patent 6,261,836) and contains 12 additional nucleotides at the 5'

untranslated end. Similarly, SEQ ID NO:13 contains the same 12 additional nucleotides at the 5' end. The reference does not suggest the specifically recited nucleotides of claim 5.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

CECH et al. (US patents 6093809 and 6309867) share an identical disclosure to 6,261,836.

Morin (US patent 6337200) provides for specific deletion variants of human telomerase

Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 5 and 33 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (571) 272-0945. The examiner can normally be reached on Tues.- Fri 8:15 AM-1:45 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1656